

**Notice of Allowability**

Application No.

10/634,689

Applicant(s)

CHOI ET AL.

Examiner

Art Unit

Lakshmi S. Channavajjala

1615

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 2-16-06.
2. ☒ The allowed claim(s) is/are 9-11.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

*The Drawings filed on 8-5-2003 have been accepted by the Examiner.*

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material

5. ☐ Notice of Informal Patent Application (PTO-152)

6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 6-22-06.

7. ☒ Examiner's Amendment/Comment

8. ☒ Examiner's Statement of Reasons for Allowance

9. ☐ Other \_\_\_\_\_.

*Lakshmi*  
**Lakshmi Channavajjala**  
Examiner  
AU 1615

## **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Hain Swope on 6-22-06.

The application has been amended as follows:

In claim 9, line 4, insert "%" after "30"

In claim 10, line 4, insert "%" after "60"

In claim 11, line 5, insert "%" after "30"

In the specification on page 1, line 7, after 2000, insert ", now U.S. Patent No. 6,627,211,"

The following is an examiner's statement of reasons for allowance:

Instant claims are directed to a pharmaceutical composition comprising an active agent (diazepam, clonazepam or (S)-2-carbamoyloxy-1-o-chlorophenyethanol) and an aqueous vehicle comprising an aliphatic alcohol of 1 to 5 carbon atoms, a glycol selected from the group consisting of propylene glycol, polyethylene glycol (PEG) 200, PEG 300, PEG 400 and PEG 600, 1% by weight of a biological surfactant selected from a group of specific bile salts and lecithin, and about 10% by volume of water. Prior art of record teaches separate vehicles comprising mixture of ethanol and glycols or vehicle

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comprising hydrophobic carriers such as such as bile salts or lecithin or glycols for administration of lipophilic drugs such as diazepam. However, the art does not recognize or suggest a vehicle or carrier comprising a combination of bile salts or lecithin, of lower alcohols and glycols, and water, in claimed amounts and for the claimed drugs. Further, while the prior art does not provide any motivation for using a vehicle with the claimed combination of components, applicants have shown that the addition of a surfactant to the mixture of a lower alcohol, a glycol and water, significantly increases the nasal absorption and bioavailability of the active agents over that observed without the surfactant and that the absorption and bioavailability achieved is comparable to that achieved by intravenous administration.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

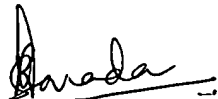
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala  
Examiner  
Art Unit 1615  
June 22, 2006